

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

SCIELE PHARMA, INC., ANDRX)
CORPORATION, ANDRX)
PHARMACEUTICALS, INC. (N/K/A WATSON)
LABORATORIES, INC.-FLORIDA), ANDRX) Civil Action No. 1:09-cv-37-RBK-JS
PHARMACEUTICALS, L.L.C., ANDRX) (Consolidated)
LABORATORIES (NJ), INC., ANDRX EU)
LTD., and ANDRX LABS, L.L.C.,)
)

Plaintiffs,)

v.)

LUPIN LTD. and LUPIN)
PHARMACEUTICALS, INC.,)

Defendants.)

) Civil Action No. 1:10-cv-00135-RBK-JS

SHIONOGI PHARMA, INC., ANDRX)
CORPORATION, ANDRX)
PHARMACEUTICALS, INC. (N/K/A WATSON)
LABORATORIES, INC.-FLORIDA), ANDRX)
PHARMACEUTICALS, L.L.C., ANDRX)
LABORATORIES (NJ), INC., ANDRX EU)
LTD., and ANDRX LABS, L.L.C.,)

Plaintiffs,)

v.)

MYLAN INC., and MYLAN)
PHARMACEUTICALS INC.,)

Defendants.)

)

STIPULATION AND ORDER OF DISMISSAL

Whereas this action for patent infringement (the “Patent Litigation”) has been brought by Shionogi Inc. (formerly Shionogi Pharma, Inc.), Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-Florida), Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd., Andrx Labs, L.L.C. (collectively “Plaintiffs”) against Defendants Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively “Mylan”) (collectively, Plaintiffs and Mylan may be referred to as “the Parties”) for alleged infringement of United States Patent Nos. 6,099,859 (“the ’859 patent”) and 6,866,866 (“the ’866 patent”);

Whereas this Court has subject matter jurisdiction over the above-captioned patent infringement action and has personal jurisdiction over the Parties;

Whereas Mylan does not contest personal jurisdiction for the purposes of the Patent Litigation;

Whereas venue is proper in this Court as to the Parties;

Whereas Mylan does not contest venue for the purposes of the Patent Litigation;

Whereas in this Patent Litigation, Plaintiffs have charged Mylan with infringement of the '859 and '866 patents;

Whereas the '859 and '866 patents are owned by Andrx Corporation, Andrx Pharmaceuticals, Inc. (n/k/a Watson Laboratories, Inc.-Florida), Andrx Pharmaceuticals, L.L.C., Andrx Laboratories (NJ), Inc., Andrx EU Ltd., Andrx Labs, L.L.C. (collectively "Andrx"), and Andrx has granted Shionogi Inc. an exclusive license to the '859 and '866 patents in the United States with regard to extended release tablets containing metformin HCl;

Whereas Andrx holds New Drug Application ("NDA") No. 21-574 for 500 mg and 1000 mg metformin HCl extended release tablets and Shionogi Inc. markets these tablets in the United States under the trade name "Fortamet®";

Whereas the '859 and '866 patents are listed for Fortamet® in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") published by the United States Food & Drug Administration ("FDA");

Whereas the commencement of the Patent Litigation by Plaintiffs was based on Plaintiffs' receipt of notice from Mylan that Mylan had filed Abbreviated New Drug Application 20-0690 (the "Mylan ANDA") with the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the '859 and '866 patents as well as U.S. Patent Nos. 6,495,162 ("the '162 patent"), 6,790,459 ("the '459 patent") and 7,919,116 ("the '116 patent") seeking approval for the commercial manufacture, use, and sale of 500 mg and 1000 mg metformin HCl extended release tablets ("Mylan's ANDA Products");

Whereas in response to the charges by Plaintiffs of patent infringement, Mylan has alleged certain defenses and counterclaims, including that the '859, '866, '162, '459 and '116 patents are invalid, unenforceable, and not infringed by Mylan's generic products defined by the Mylan ANDA;

Whereas Plaintiffs have not asserted any charges of infringement against Mylan with respect to the '162, '459 and '116 patents, but Mylan has asserted certain defenses and counterclaims for these patents;

Whereas, to date, this Court has not ruled on Plaintiffs' charges of patent infringement against Mylan, nor Mylan's defenses and counterclaims;

Whereas, no Party concedes that its claims, defenses, or counterclaims lack merit;

Whereas the Patent Litigation has been hard fought and expensive to Plaintiffs and to Mylan;

Whereas the Parties have entered into a good-faith final Settlement and License Agreement regarding this Patent Litigation, on the expectation and belief that this settlement would eliminate the substantial litigation costs, risks, and uncertainty that would otherwise be incurred and experienced by the parties during the Patent Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the Parties associated with continued litigation;

Whereas the reasonable final settlement will afford the Parties the pro-competitive opportunity to more productively use resources that would have been spent in the continued prosecution and defense of this Patent Litigation, to the benefit of the Parties and consumers alike, such as by investing more resources into pharmaceutical research and development;

Whereas under the Settlement and License Agreement entered into by the Parties, Mylan was granted the right to market generic versions of products covered by the '859, '866, '162, '459 and '116 patents no later than August 1, 2013, allowing entry of generic versions of Fortamet® over seven years in advance of the March 17, 2021 expiration of the '866 patent;

Whereas the Parties acknowledge there is significant risk and uncertainty to each of them associated with continued prosecution and defense of this Patent Litigation, and each has consented to entry of this Order of Dismissal through a final settlement as reflected herein;

Whereas this settlement resolves all litigation involving the Mylan ANDA among the Parties;

In consideration of the above factual representations, the request and consent of the Parties and upon due consideration of the Settlement and License Agreement, **IT IS HEREBY ORDERED, ADJUDGED, AND DECREED THAT:**

1. All claims, counterclaims, and affirmative defenses presented by the Parties in this Patent Litigation are hereby dismissed with prejudice;
2. The Parties agree to be bound by the terms of the Settlement and License Agreement;
3. Shionogi Inc., Andrx, and Mylan, each expressly waives any right to appeal or otherwise move for relief from this Order of Dismissal;
4. This Court retains jurisdiction over the Parties for purposes of enforcing and interpreting this Order of Dismissal;
5. The Clerk of the Court is directed to enter this Order of Dismissal forthwith.

Dated: March 13, 2013

MORRIS NICHOLS ARSHT & TUNNELL LLP

/s/ Karen Jacobs Louden

Jack B. Blumenfeld (I.D. #1014)
Karen Jacobs Louden (I.D. #2881)
1201 North Market Street
Wilmington, Delaware 19801-1494
(302) 658-9200
jblumenfeld@mnat.com
klouden@mnat.com

Of Counsel:

David B. Bassett
David A. Manspeizer
Christopher R. Noyes
WILMERHALE LLP
7 World Trade Center
250 Greenwich Street
New York, NY 10007
(212) 230-8800

Attorneys for Shionogi Pharma, Inc.

MORRIS JAMES LLP

/s/ Mary B. Matterer

Mary B. Matterer (I.D. #2696)
Richard K. Herrmann (I.D. #405)
500 Delaware Avenue, Suite 1500
Wilmington, Delaware 19801-1494
(302) 888-6800
mmatterer@morrisjames.com
rhermann@morrisjames.com

Of Counsel:

Timothy H. Kratz
Robert L. Florence
George J. Barry III
Anil H. Patel
Micheal L. Binns
Karen L. Carroll
MC GUIREWOODS LLP
1230 Peachtree Street, Suite 2100
Atlanta, Georgia 30309
(404) 443-5500

Attorneys for Mylan Inc. and Mylan Pharmaceuticals Inc.

RICHARDS, LAYTON & FINGER PA

/s/ Steven J. Fineman

Frederick L. Cottrell , III (I.D. #2555)
Steven J. Fineman (I.D. #4025)
920 N. King Street
Wilmington, DE 19801
(302) 651-7700
cottrell@rlf.com
fineman@rlf.com

Of Counsel:

Gary E. Hood
POL SINELLI SHUGHART PC
161 N. Clark Street, Suite 4200
Chicago, IL 60606
(312) 819-1900

*Attorneys for Andrx Corporation, Andrx Pharms., Inc.
Andrx Pharmaceuticals, L.L.C., Andrx Labs. (NJ), Inc
Andrx EU, Ltd. and Andrx Labs, L.L.C.*

IT IS HEREBY SO ORDERED.

Dated: _____

THE HONORABLE ROBERT B. KUGLER
United States District Judge
District Of New Jersey

7050489